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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/008,778	11/13/2001	Eric Hauser Kuhrts	68911-076	4731

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EXAMINER	
MELLER, MICHAEL V	

ART UNIT	PAPER NUMBER
1655	

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11/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/008,778	KUHRTS, ERIC HAUSER	
	Examiner	Art Unit	
	Michael V. Meller	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,16 and 18-27* is/are pending in the application.

4a) Of the above claim(s) *1-12,14,16 and 18-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

The restriction requirement of record is maintained for the reasons of record. Claims 1-12, 14, 16, 18-27 are withdrawn from further consideration since they are drawn to non-elected subject matter. The restriction requirement has already been made **FINAL** as noted by applicants.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 13 is rejected under 35 U.S.C. 112, first paragraph, because the specification is not enabled for treating osteoarthritis, rheumatoid arthritis and acute pain using a therapeutically effective amount of a bioavailable pharmaceutical composition comprising a therapeutic quantity of a COX-2 inhibitor having an IC50-WHMA COX-2/COX-1 ratio ranging from about 0.23 to about 3.33 with reduced gastrointestinal and cardiovascular toxicity to a mammal having osteoarthritis, rheumatoid arthritis and acute pain wherein the amount of the COX-2 inhibitor ranges from about 5 mg to about 1000 mg per day. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation. The factors include:

1) the nature of the invention;
2) the breadth of the claims;
3) the predictability or unpredictability of the art
4) the amount of direction or guidance presented;
5) the presence or absence of working examples;
6) the quantity of experimentation necessary;
7) the state of the prior art; and,
8) the relative skill of those skilled in the art;

With respect to the Wands factors above, applicants have not enabled a method of treating osteoarthritis, rheumatoid arthritis and acute pain using a therapeutically effective amount of a bioavailable pharmaceutical composition

comprising a therapeutic quantity of a COX-2 inhibitor having an IC50-WHMA COX-2/COX-1 ratio ranging from about 0.23 to about 3.33 with reduced gastrointestinal and cardiovascular toxicity to a mammal having osteoarthritis, rheumatoid arthritis and acute pain wherein the amount of the COX-2 inhibitor ranges from about 5 mg to about 1000 mg per day.

The nature of the invention is to treating osteoarthritis, rheumatoid arthritis and acute pain using a therapeutically effective amount of a bioavailable pharmaceutical composition comprising a therapeutic quantity of a COX-2 inhibitor having an IC50-WHMA COX-2/COX-1 ratio ranging from about 0.23 to about 3.33 with reduced gastrointestinal and cardiovascular toxicity to a mammal having osteoarthritis, rheumatoid arthritis and acute pain wherein the amount of the COX-2 inhibitor ranges from about 5 mg to about 1000 mg per day.

The breadth of the claims is enourmous. The specification does not provide disclosure for treating osteoarthritis, rheumatoid arthritis and acute pain using a therapeutically effective amount of a bioavailable pharmaceutical composition comprising a therapeutic quantity of a COX-2 inhibitor having an IC50-WHMA COX-2/COX-1 ratio ranging from about 0.23 to about 3.33 with reduced gastrointestinal and cardiovascular toxicity to a mammal having osteoarthritis, rheumatoid arthritis and acute pain wherein the amount of the COX-2 inhibitor ranges from about 5 mg to about 1000 mg per day. None of the diseases/conditions were tested *in vivo* and no positive conclusions were ever drawn. No data showing how the patients did is ever presented. How does one really know that the osteoarthritis, rheumatoid

arthritis and acute pain were actually effectively treated ? To envision anyone having acute pain for example includes anyone for the reasons of record. Thus, the claims are unduly broad.

The unpredictability in the art is high since treating osteoarthritis and rheumatoid arthritis can be complicated and non-predictable from patient to patient. Further, rheumatoid arthritis and osteoarthritis are completely different forms of arthritis which are very different in their mechanisms, thus making it unpredictable to determine without *in vivo* data whether treatment of one of the claimed conditions will work in another of the claimed conditions.

The amount of direction in the specification (including examples) is stating that people with osteoarthritis, rheumatoid arthritis and acute pain can be tested but none actually were. This is almost no guidance whatsoever to one having ordinary skill in the art. The treatment of all three of these conditions/diseases is completely different. Osteoarthrtis versus rheumatoid arthritis as stated above are totally different since the two forms of arthritis are totally different in nature. Knowing only that a patient (in vivo) can be treated with the claimed COX-2 inhibitor (which the specification does not show) does not mean that the arthritis will actually be treated as claimed.

The quantity of experimentation needed to show that one of ordinary skill in the art can treat osteoarthritis, rheumatoid arthritis and acute pain using a therapeutically effective amount of a bioavailable pharmaceutical composition

comprising a therapeutic quantity of a COX-2 inhibitor having an IC50-WHMA COX-2/COX-1 ratio ranging from about 0.23 to about 3.33 with reduced gastrointestinal and cardiovascular toxicity to a mammal having osteoarthritis, rheumatoid arthritis and acute pain wherein the amount of the COX-2 inhibitor ranges from about 5 mg to about 1000 mg per day is quite high. While it is not impossible, applicant needs to show that patients having osteoarthritis and rheumatoid arthritis were actually tested with the claimed composition. The good news is, that it is possible to do this, but is needed since the specification is devoid of such critical information.

The state of the prior art is that there is no treatment of osteoarthritis or rheumatoid arthritis using a therapeutically effective amount of a bioavailable pharmaceutical composition comprising a therapeutic quantity of a COX-2 inhibitor having an IC50-WHMA COX-2/COX-1 ratio ranging from about 0.23 to about 3.33 with reduced gastrointestinal and cardiovascular toxicity to a mammal having osteoarthritis or rheumatoid arthritis wherein the amount of the COX-2 inhibitor ranges from about 5 mg to about 1000 mg per day.

The skill level of those in this art is quite high, that of the level of a PhD in biochemistry.

Thus, the claims do not find enablement from the instant specification.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rigby et al. (US 3354219) in view of Todd, Jr. et al. (US 5041300) and as evidenced by Medicinenet.com and About.com.

4. Rigby teaches that hot water, NaOH, and hops are boiled for two hours, see col. 4, lines 5-70. The reference also notes that KOH (potassium hydroxide) can be used instead of NaOH. It is noted that the composition has a milder odor and flavour thus someone drank the composition. Medicine net makes it clear that acute pain comes on quickly thus it reads on anyone since anyone can have acute pain. About.com makes it clear that standarized extracts have been processed to contain a specific amount of a compound but as see in Rigby once the extract is reacted with the KOH a specific amount of iso-alpha acids are formed, namely 2.4 g of isohumulones, see col. 4, lines 15-25.

5. Rigby does not teach the claimed amount of COX-2 inhibitor.

6. Todd teaches that 50 ppm of isoalpha acids were added to beer, see col. 13, lines 25-40.

In the event that using the KOH instead of NaOH is seen as obviousness instead of anticipation, (which this examiner highly doubts) it still would been obvious to one having ordinary skill in the art to use the KOH instead of the NaOH since Ribgy clearly indicates that "obvious commercial alternatives are possible" and then goes on to list KOH as one of the options. Clearly the KOH was envisioned to be used instead of the NaOH.

Further it would have been obvious to use the claimed amount of COX-2 inhibitor since Todd makes it clear that 50 ppm of isoalpha acids were added to beer to yield beneficial results, see col. 13, lines 25-40 of Todd. This translates to 50 mg/liter which clearly would provide motivation for one of ordinary skill in the art to use the iso alpha acids of Rigby at a concentration of 5 mg to 1,000 mg per day since in Rigby one is consuming beer as they are in Todd and 3 beers would be equivalent to one liter which would equate to 50 mg. One beer would equate to 17.75 mg which is well within the claimed range as well. Thus, the claimed invention is obvious.

Applicant argues that Rigby does not teach that the claimed composition can treat the claimed conditions. It was established on the record already that anyone suffers from acute pain for the reasons of record, thus the claimed invention reads on administration to anyone thus the claims are met by Rigby. Applicant then argues that the amount of the composition was not taught but this was taught by Todd for the reasons of record.

Medicine.net was stated as only providing a definition of acute pain but this states and establishes that acute pain reads on anyone, not any particular patient population, we all have pain.

Applicant then argues that Todd does not teach treatment of the claimed conditions, but as stated above, the claimed condition, acute pain, is suffered by anyone.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claim 13 is provisionally rejected on the ground of nonstatutory double patenting over claims 8-10, 13-15 of copending Application No.11409521. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: the claims of the application (11409521) claim a condition which can read on acute pain and as disclosed rheumatoid arthritis and osteoarthritis.

9. Claim 13 is rejected on the ground of nonstatutory double patenting over claims 1-7, 9-23 of U. S. Patent No. 7279186 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: the patent claims treating inflammation and as defined in the specification of the patent includes osteoarthritis, acute pain and rheumatoid arthritis.

If applicant is aware of any other applications/patents which would constitute an Obviousness type double patenting rejection (such as the ones above), applicant is required to put such evidence on the record and submit terminal disclaimers to obviate those applications/patent as well as the above listed ones.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael V. Meller/
Primary Examiner, Art Unit 1655